REMARKS

The Office action dated May 15, 2006 is acknowledged. Claims 1-8 are pending in the instant application. According to the Office action, claims 1-8 have been rejected. Reconsideration of the rejection of claims 1-8 is respectfully requested in light of the above amendments and following remarks.

Rejection of Claims 1-8 under 35 U.S.C. 112

Claims 1-8 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The Examiner stated that the term "active substance film" is unclear. The following is an explanation of the term "active substance film."

The specification clearly states that the invention relates to wafers which are dosage forms (also referred to as administration forms) for medicaments (see paragraphs [00002-00003]). In the manufacturing process, the wafers are produced by cutting the active substance film (see paragraph [00002-000010]). Hence, the "active substance film" and the wafer produced from this film by cutting consist of the same material. The film materials that are suitable for making medicament-containing wafers are well known in the art. In the introductory section of the present specification (paragraphs [00004, 00005]), reference is made to DE 198 00 682 A1 which is the priority application of US 6,655,112 (Cremer et al.) cited by the Examiner. US 6,665,112, in columns 1 and 2, provides a general overview on the wafer-like administration forms, as well as further

references describing such wafers in detail (column 1, lines 16-17). US Patent 4,136,162, partial copy enclosed, (corresponding to DE 24 32 925 cited by Cremer et al.) describes various examples of film-shaped medicament carriers. It should also be mentioned that wafers are standard dosage forms which are listed in the "CDER Data Standards Manual" issued by the FDA, a copy of the relevant portion which is enclosed).

In conclusion, a person skilled in the art of pharmaceutical dosage forms will be familiar with the types of materials and compositions that are used for making the "active substance films" mentioned in the application and claims. While the term "active substance film" does not require a specific material or composition, it is restricted to such types of materials or compositions that are suitable for producing active substance-containing wafers as defined in paragraph [00003] of the specification. The term "active substance film" requires the film to contain an active substance which is a drug substance (for medicaments as mentioned in paragraph [00003] of the specification).

Therefore, it is respectfully submitted that the Examiner misinterpreted the meaning of "active substance film" to mean "any film with a front end, two sides and a predetermined length." Also, claim 1 has been amended and no longer includes the limitation "active substance film having a front end, two sides and a predetermined length."

Based on the above description of the "active substance film", the Applicant respectfully requests that the 112 rejection of claims 1-8 be withdrawn.

The Examiner has also stated that the term "wafer" is unclear with reference to claim 1. The following is an explanation of the term "wafer."

As stated in the explanation above, the Applicant submits that the term "wafer" is sufficiently clear, since a person skilled in the art is familiar with the structure and composition of wafers that are used as dosage forms. The Examiner's definition of a wafer – "a cut portion of the active substance film" – is essentially correct, but the above considerations relating to active substance films and dosage forms must be additionally taken into account.

The Examiner's rejection of the term "wafer" as being unclear was partly due to the phrase "detaching said active substance film from the carrier and the wafer" in claim 1 which has now been amended by deleting the phrase "and the wafer." Hence, the Applicant believes that the term "wafer" is now clear and respectfully requests the 112 rejection of claims 1-8 be withdrawn.

The Examiner also stated that with reference to claim 1, the Applicant discloses two sealing steps, but only discloses one sealing step in the specification. Further, the Examiner states that the Applicant discloses two cutting steps in claim 1, but only one cutting step in the specification. The Applicant has amended claim 1 as set forth above. The Applicant now believes that the 112 rejection of claims 1-8 is overcome, and respectfully requests the rejection to be withdrawn.

Rejection of Claims 1-5 under 35 U.S.C. 102(e)

Claims 1-5 have been rejected under 35 U.S.C. 102(b) as being anticipated by Cremer et al (Cremer) (US 6,655,112). According to the Examiner, Cremer teaches each and every feature of the present invention set forth in claims 1-5.

The Applicant respectfully disagrees with the Examiner, and submits that Cremer does not disclose all of the features of the present invention. Claim 1 pertains to a process for manufacturing and for packing wafers. The dose of active substance contained in the wafer is dependent on the surface area of the wafer (see paragraph [00003] of the specification). According to the claimed process, the length of each wafer is determined by pulling the carrier sheet (and the active substance film that is connected to the carrier sheet) as required to adjust this length. The width of each wafer is determined by the width of the laminate used. By cross-cutting the film as defined in claim 1, wafers having a defined length and width, and hence a defined surface area, are obtained. One of the key features of the presently claimed manufacturing process is that the active substance-containing material is never stretched or subject to mechanical stress prior to cross-cutting (see paragraphs [00003, 000008 and 000010]).

The following are differences between Cremer and the presently claimed invention. Claim 1, as presently amended, requires the following sequence of process steps: partially detaching the active substance film from the carrier; pulling the carrier sheet to advance the detached film by the predetermined length of the wafer; inserting the detached film between the two packaging material webs while the region of the film which will form the wafer is still connected to the upstream film; thereafter, cross-cutting the film to produce an individual wafer.

Cremer fails to teach a process by which an active substance-containing film is inserted between two packaging webs while it is still partially connected to a carrier web, and is then cross-cut to obtain an individual wafer. According to the embodiment of

Cremer's Figure 1, the film does not comprise a carrier, resulting in stretching or mechanical stress when the film is pulled by the pulling devices. Figure 2 of Cremer does not disclose a cross-cutting step (only punching), and punching is performed prior to detaching the film from the carrier (see Figure 2). At the time when the film is introduced between the packaging material webs, the punching step is already completed. According to the present claim 1, the film is first detached and is then cross-cut in a subsequent step.

Also, Figure 2 of Cremer fails to disclose the step of "pulling said carrier sheet, and thereby also the active substance film, forward over the predetermined length of the wafer." Since the length of the wafer, in Figure 2, is determined by the shape of the punching tool, the length of the pulling movement is irrelevant in this respect. Figure 1 of Cremer does not disclose this step either, as this embodiment does not provide the use of a carrier material. Based on the description provided by Cremer, it also appears unknown whether the packaging material webs remain in a resting condition as the film is inserted between them (see present claim 1).

Cremer basically discloses two different methods for producing and packaging active substance-containing wafers. According to the first embodiment shown in Figure 1, the film-like active substance-containing material 4, which does not comprise a carrier sheet, is conveyed by pulling devices 17 in the form of rolls or tongs (column 6, last paragraph to column 7, first paragraph). Clearly, when the film-like material is pulled over the rolls or tongs, it becomes stretched or is exposed to mechanical stress which according to the present invention is to be avoided. The length of the resulting wafer is

determined by the distance over which the film is advanced by the pulling devices 17. According to the second embodiment shown in Figure 2 of Cremer, wafers are punched out from a laminate 13 comprising a carrier sheet 14 and an active substance-containing film 4. Punching occurs prior to detaching the film from the carrier; therefore, it is important that only the film 4, but not the carrier 14 is punched through (column 7, lines 23-37). The length (and width) of the wafer is exclusively determined by the shape of the punching tool 15.

The Examiner's interpretation of Cremer's teaching is flawed since it combines various features which are disclosed separately in the two basic embodiments of Figures 1 and 2 of Cremer.

With regard to the teaching of a "laminate comprising a carrier sheet 14 and an active substance film", Cremer teaches such laminate only in connection with the second embodiment in which the individual wafers are produced by punching-out rather than by cross-cutting. On the other hand, in the embodiment of Figure 1 in which wafers are produced by cross-cutting, the active substance film 4 does not comprise a carrier.

Furthermore, the Examiner's interpretation suggests the embodiment of Figure 2 of Cremer shows "cross-cutting the active substance film at the predetermined length (15)." However, reference numeral 15 relates to a punching device (column 7, lines 28-33) rather than to a cross-cutting device. When the wafers are formed by punching (as in Figure 2), it would not make any sense to cross-cut the active substance film at a predetermined length, as the length of the wafer is determined by the shape of the punching tool. Cross-cutting means that the film is cut transversely over its entire width,

resulting in square or rectangular dosage units (column 6, last paragraph). In contrast, punching does not result in a cut that runs over the entire width (see Figure 3 of Cremer; dosage units 5). Cremer teaches laminates (comprising film and carrier) only in combination with the punching method, but not in combination with the cross-cutting method. Combining both embodiments taught by Cremer results in a new combination which was not unambiguously disclosed by Cremer.

With respect to claim 2, Cremer does not disclose a vertical alignment of active substance film and packaging webs. Figures 1 and 2 of Cremer show a horizontally arranged device, as judged from the orientation of the reference numbers and the arrows indicating upward/downward movements in Figure 1. (See also the Examiner's comment on page 6 of the Office action: "Cremer is silent as to the orientation of the device").

Concerning dependent claim 5, the Examiner has interpreted the "corner pulleys 3" disclosed by Cremer as being equivalent to the clamping device mentioned in present claim 5. However, this is not the case. A clamping device is a device that can switch or alternate between a clamping position and an open position (see present claim 7). In contrast, a pulley is just a pulley, and nothing in Cremer's teaching suggest that the corner pulleys might act as a clamping device. The function of the clamping rollers of the present invention is shown in Figures 2-5. When the clamping rollers are in the open or receiving position (as shown in Figure 2), the active substance-containing film can be inserted between the packaging webs without subjecting the film to mechanical stress, as required by present claim 1.

Further, because claims 2-5 depend directly from claim 1, claims 2-5 are also not anticipated by Cremer for the reasons set forth above regarding claim 1.

In view of the above arguments and amendments, the Applicant respectfully submits that the Cremer fails to teach every limitation set forth in the claims 1-5. Therefore, this rejection is not proper and therefore the withdrawal thereof is requested.

Rejection of Claim 6 under 35 U.S.C. 103(a)

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Cremer and in view of US Patent No. 5,182,128 to Laplace.

According to the Examiner, Cremer discloses all of the elements of the presently claimed invention, but is silent as the orientation of the device (horizontal/vertical). However, Cremer fails to teach "a receiving and clamping device" as discussed above with dependent claim 5.

With respect to the horizontal orientation of the invention, the Examiner has cited Laplace discloses a device that is operated vertically. The Examiner submits the motivation would have been to improve feeding to the assembly and prevent blockage of the assembly. However, a person skilled in the art would realize that the vertical orientation of Laplace's device is necessitated by the physical properties of the food material which is fluid or semifluid (column 2, lines 25-30). In contrast, the device of the present invention is specifically designed to process active substance-containing laminates which are solid rather than fluid. Therefore, Laplace could not have provided

any motivation to arrange the receiving and clamping device in a vertical direction as specified in present claim 6.

Therefore, since neither Cremer nor Laplace disclose any clamping devices, and since Laplace could not provide any motivation for arranging any clamping devices (which were not disclosed anyhow) in a vertical direction, the presently claimed invention would not have been obvious to a person skilled in the art.

Rejection of Claim 7-8 under 35 U.S.C. 103(a)

Claims 7-8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Cremer as applied to claim 6 above, and further in view of US Patent No. 5,985,088 to Couillard et al. in view of Laplace.

The Examiner stated with respect to claim 7, Cremer discloses a method of packaging film-like shapes, including a clamping device, but does not disclose the clamping device is movable.

As noted above, the "corner pulleys 3" shown in Figure 2 of Cremer cannot be considered clamping devices. Therefore, Cremer does not disclose clamping devices as in the presently claimed invention.

Couillard (column 4, lines 57-63) teaches using movable clamping rollers "when the substrate is relatively thick." However, in the case of the present invention, the substrate is relatively thin (a "wafer"; see paragraph [00003] of the present specification; Cremer, column 1). Therefore, in accordance with Couillard's teaching, when the substrate is thin, there is no need for using movable clamping rollers.

In contrast, the movable clamping devices as shown in Figures 2-5 of the present invention are capable of alternating between a receiving position and a closed or clamping position. When the clamping devices are in the receiving position, the front end of the active substance film can be inserted between the packaging webs, after which these devices shift to the clamping position in order to fix the active substance film between the packaging webs (see present specification, paragraphs [000019-000020]). In other words, the clamping devices, in each production cycle, switch between receiving position and clamping position (see paragraphs [000019-000020]: "preceding cycle...next cycle"). This function is fundamentally different from the function suggest by Couillard (column 4, lines 57-63) which is restricted to adjusting the rollers to accommodate the thickness of the substrate.

Further, due to the fact that the wafers of the present invention contain active substances and are used as drug administration forms, the thickness of these wafers must be highly constant. This, of course, applies also to the film layer from which they are produced. Therefore, as it is an essential requirement for pharmaceutical wafers to have an essentially constant thickness, there was no necessity to "accommodate different thicknesses of the film", and a person skilled in the art would not have applied Couillard's teaching to Cremer and Laplace to obtain a device for making such wafers. As noted above, neither Cremer nor Laplace disclose any clamping devices as required by the present invention.

The Examiner stated with respect to claim 8, Cremer discloses a method of packaging film-like shapes, including a clamping device, but does not disclose the clamping device is movable.

As explained above, there was no motivation "to accommodate different thicknesses of film." Therefore, a person skilled in the art would not have considered combining Couillard with Cremer and Laplace. It is also noted that while Couillard, in Figure 2, appears to disclose two pairs of rollers with a substrate being transported between the rollers of each pair, these pairs of rollers are not "arranged one above the other" as in the Applicant's claim 8, but rather in a side-by-side arrangement (rollers 40, 42 on the right, rollers 50, 52 on the left side). Even if Couillard would be combined with Cremer and Laplace, this would not have resulted in the invention claimed in present claim 8, as none of these references disclose any feeding/pulling devices which comprise a receiving and clamping device.

Therefore, since neither Cremer nor Laplace disclose any clamping devices, and since Couillard does not provide any motivation to accommodate different thicknesses of the film, the presently claimed invention would not have been obvious to a person skilled in the art. The Applicant respectfully requests the 103 rejection be withdrawn.

Conclusion

Based on the above amendments and the above arguments, it is believed that the present application is in condition for allowance, and such action is earnestly solicited. The

Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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